REMARKS

Claim Status

Claim 1 has been amended to recite a feed composition comprising an animal feed, about 2.5% to about 10% by weight of triglycerides containing C_4-C_{12} medium chain fatty acids, and about 1,000 ppm to about 10,000 ppm of exogenous active lipolytic enzyme.

As to the above amendment of "about 2.5 to about 10%", support is found in former claim 32, which has subsequently been cancelled, as well as in Table 9, on pages 19-20 of the instant specification.

As to the above amendment of "about 1,000 ppm to about 10,000 ppm", support is found in Table 2, on page 11 of the instant specification, wherein 1,000 ppm of lipase (L2 or L5) was used in each of the feeds, as well as in Table 9, on pages 19-20 of the instant specification, wherein it shows that a higher dose of L5 corresponds to a higher concentration of free fatty acids released *in vitro*, which further corresponds to a more pronounced suppression of the number of bacteria (i.e., a stronger antibacterial activity). In addition, Table 9 also demonstrates that when using 100 ppm of L5 in the feed composition, the bacterial counts are at the similar levels as those obtained in the control group. This result suggests that a feed composition comprising 100 ppm of a lipolytic enzyme does not appear to provide a significantly improved antibacterial activity compared to the controls. In view of the disclosure from the instant specification, Applicants believe that adequate support is indeed provided for amending the lower limit of the lipolytic enzyme concentration from "100" ppm to --1,000 ppm--.

As to the above amendment of "exogenous" active lipolytic enzyme, support is found on page 3, line 32; page 4, line 3; and page 5, lines 10 and 15 of the instant specification.

Claims 9-11 have been amended to refer to the proper antecedent basis as well as for formality reasons that are not related to patentability.

Claim 21 has been amended for formality reasons that are not related to patentability.

Claim 27 has been amended to further limit the triglycerides as recited in claim 1 to those consisting of C_6 to C_{12} medium chain fatty acids. Support for this amendment is found in Table 1, on page 10 of the instant specification.

Claims 12, 28 and 30 have been cancelled.

Claims 29 and 31 have been amended to clearly define the claimed feed composition with particularity by removing the terms "synthetic" and "commercial" therefrom, respectively, and further by replacing the phrase "based on" with the term --comprises--. In addition, claims 29 and 31 have been amended to correct the dependencies as a result of the cancellation of claims 28 and 30, respectively.

Pursuant to 37 C.F.R. §1.118(a), Applicants respectfully submit that the above amendments do not introduce any new material into the application. With the present amendments, 11 claims are pending in the application, namely, claims 1-3, 9-11, 21, 26-27, 29 and 31.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 12 and 28-32 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In particular, the Examiner states that the recitation of "commercially available", "synthetic", "based on" or "commercial" in claim 12, 28, 29, 30 or 31 is vague and indefinite. In response, Applicants have amended claims 29 and 31 to clearly define the claimed feed composition with particularity as discussed above under the section titled "Claim Status". In addition, Applicants have cancelled claims 12, 28 and 30.

The Examiner further states that claim 32 is vague, indefinite and confusing for the recitation of "consisting essentially of". In response, Applicants submit that claim 32 does not recite this phrase. However, claim 32 has been cancelled as a result of present amendments made to claim 1, which amendments include incorporation of the subject matter of claim 32 into claim 1.

With respect to the transitional phrase "consist essentially of", Applicants note that claim 27, which formerly recites this phrase, has now been amended to recite the phrase "consist of" with the adequate support from the instant specification as pointed out above under the section titled "Claim Status". Applicants submit that claim 27, as presently amended, clearly indicates that the materials to be excluded by the recitation of "consist of" are C_4-C_5 medium chain fatty acids. Although the open-end language "comprising" is used in its base claim (i.e., claim 1), Applicants assert that claim 27 presents no confusion as to what materials are to be excluded from the category of the triglycerides containing C_4-C_{12} medium chain fatty acids as well as what materials could be included in the category of the feed composition, as the recitations of "consist of" and "comprising" are referring to substances of different categories.

It is believed that the claims as presently amended are definite and that the rejection under 35 U.S.C. § 112, second paragraph, is now overcome.

Rejections under 35 U.S.C. § 102

Claims 1-3, 9-12, 21 and 26-27 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Melichar *et al.* or Nars or Salle *et al.* as evidenced by Tang *et al.* and Hurley. Applicants respectfully traverse this rejection.

Claim 1 as presently amended refers to a feed composition comprising an animal feed, about 2.5% to about 10% by weight of triglycerides containing C_4-C_{12} medium chain fatty acids,

and about 1,000 ppm to about 10,000 ppm of exogenous active lipolytic enzyme. As discussed above under the section titled "Claim Status", such amendments to claim 1 are in correlation with the working examples of the instant specification, which examples describe that feed compositions having 2.5%, 5% or 10% triglycerides and 1,000 ppm or 10,000 ppm of exogenous lipolytic enzymes have advantageous properties such as improved antibacterial activities compared to controls (*see*, Experiment 4, Table 9.)

Melichar *et al.,* Nars, Salle *et al.* or Suranyi *et al.* discloses lyophilized human milk. None of these references teaches or suggests a feed composition comprising in addition to an animal feed, about 2.5 to about 10% of triglycerides containing C_4-C_{12} medium chain fatty acids as well as about 1,000 ppm to about 10,000 ppm of exogenous active lipolytic enzyme.

Tang *et al.* discloses a dietary composition comprising a nutritional base containing fats and an effective amount of bile salt activated lipase. Tang *et al.* further discloses that human skim milk contains about 0.1 mg/ml bile salt activated lipase (BAL) (column 4, line 39). However, Tang *et al.* does not disclose a feed composition that comprises in addition to an animal feed, about 2.5 to about 10% of triglycerides containing C_4-C_{12} medium chain fatty acids, and about 1,000 ppm to about 10,000 ppm of exogenous active lipolytic enzyme.

Hurley is a general disclosure on breast milk and lactation. In particular, Hurley discloses that human or bovine breast milk contains 4% triglycerides (in the table of page 2). However, Hurley does not disclose a feed composition that comprises in addition to an animal feed, about 2.5 to about 10% of triglycerides containing C_4-C_{12} medium chain fatty acids as well as about 1,000 to 10,000 ppm of exogenous active lipolytic enzyme. In fact, Hurley teaches that the lipids synthesized in the mammary gland are C_{12} to C_{16} medium chain fatty acid (*see*, page 4, paragraph titled "Synthesis of milk lipid").

Although Tang *et al.* and Hurley together might teach that breast milk from humans and other animals contains about 4% triglycerides and about 100 ppm of active bile salt activated lipase, none of the references cited by the Examiner teaches a feed composition comprising in addition to an animal feed, about 2.5 to about 10% of triglycerides containing C_4-C_{12} medium chain fatty acids as well as about 1,000 ppm to about 10,000 ppm (emphasis added) of exogenous active lipolytic enzyme. As such, the present novelty rejection should be traversed.

Rejection under 35 U.S.C. § 103

Claims 1-3, 9-12, 21 and 26-31 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hull *et al.* taken with Haas *et al.* and Tang *et al.* Applicants respectfully traverse this rejection.

Claim 1 has been amended to recite a feed composition comprising an animal feed, about 2.5 to about 10% triglycerides containing C_4-C_{12} medium chain fatty acids, and about 1,000 to about 10,000 ppm of exogenous active lipolytic enzyme.

Hull *et al.* discloses a method of producing sweet cream buttermilk from lipolyzed creams. Hull *et al.* is completely silent on a composition comprising in addition to an animal feed, about 2.5 to about 10% of triglycerides containing C_4-C_{12} medium chain fatty acids as well as about 1,000 ppm to about 10,000 ppm of exogenous active lipolytic enzyme.

Haas *et al.* discloses a composition comprising fat and protein, which has been conditioned by emulsifying the fat and treating the mixture with lipase and protease. Haas *et al.* further discloses that during the treatment, the fat reacts with the lipase to produce free fatty acids and mono- and diglycerides (emphasis added). *See* column 2, lines 17-19. Clearly, Haas *et al.* does not teach or suggest a feed composition comprising an animal feed, triglycerides

(emphasis added) containing C_4-C_{12} medium chain fatty acids, as well as exogenous active lypolytic enzymes.

As discussed above, Tang *et al.* does not disclose a feed composition that comprises in addition to an animal feed, about 2.5 to about 10% of triglycerides containing C_4-C_{12} medium chain fatty acids as well as about 1,000 ppm to about 10,000 ppm of exogenous active lipolytic enzyme.

None of the Hull *et al.*, Haas *et al.* and Tang *et al.* teaches or suggests a feed composition comprising in addition to an animal feed, about 2.5 to about 10% of triglycerides containing C_4-C_{12} medium chain fatty acids as well as about 1,000 ppm to about 10,000 ppm (emphasis added) of exogenous active lipolytic enzyme. Even if one of ordinary skill in the art were motivated to combine the teachings of Hull *et al.*, Haas *et al.* and Tang *et al.*, he or she would not have produced the present invention as claimed.

Applicants further submit that the feed composition as claimed in the present application alleviates and/or prevents health problems encountered by animals in their early growth, which advantageous effects are clearly demonstrated in the instant specification, for instance, in Experiment 4, on pages 18-21. The combination of about 2.5 to about 10% by weight of C_4-C_{12} medium chain fatty acid-containing triglycerides and about 1,000 to about 10,000 ppm of exogenous active lipolytic enzymes surprisingly results in a physiological environment in the stomach of the animal being treated which regulates and stabilizes the gastrointestinal microflora. This effect, combined with the fact that an easily digestible and metabolizable source of energy is provided, further surprisingly results in a marked improvement of the growth which is comparable with the growth promotion obtained with the commonly used (and contested) antibiotics and other growth enhancers without negative side effects for the animal, the feed industry and the consumer.

The instantly claimed feed composition shows an unexpectedly high bacteriostatic and bactericidal activity against Gram-positive and Gram-negative bacteria (*see* instant specification, page 7, lines 17-18; Experiment 2, Table 3; Experiment 4, Table 9.) As discussed above under the section titled "Claim Status", the high dose of the exogenous lipolytic enzymes comprised in the feed composition, i.e., in the range of from about 1,000 ppm to about 10,000 ppm, play an important role in providing a significantly improved antibacterial activity compared to the controls. Such high dose of the exogenous lipolytic enzymes is crucial for early-weaned animals, which helps to overcome the pronounced deficiency of endogenous lipolytic enzymes observed in these animals shortly after weaning (*see*, page 7 lines 29-32 of the instant specification).

Furthermore, the instantly claimed feed composition prevents digestive upsets and has a positive effect on growth without negative side effects (*see*, page 8, lines 7-16 of the instant specification). These surprising properties are due to the combined effect of the C_4-C_{12} medium chain fatty acid-containing triglycerides and the high dose of exogenous lipolytic enzyme comprised in the composition. Indeed, the addition of the exogenous lipolytic enzymes increases the hydrolysis of the triglycerides by about three folds compared to endogenous lipolytic activity (*see*, Table 4; and line 36, page 13 thru line 8, page 14 of the instant specification). The increased hydrolysis of the triglycerides by the exogenous lipolytic enzymes results in the increased release of free medium chain fatty acids in the stomach of the animal being treated, which release has a sterilizing effect providing thereby the therapeutic effects cited above.

In view of the above remarks, neither the feed composition as presently claimed, nor the above-mentioned unexpected benefits provided by such compositions, would have been apparent from Hull *et al.*, Haas *et al.*, and Tang *et al.*, alone or combined. Therefore, Hull *et al.* taken

with Haas *et al.* and Tang *et al.* would not have rendered obvious the present invention as claimed. Applicants respectfully request that the rejection under 35 U.S.C. 103 be traversed.

Comments re Examiner's Response to Arguments

The Examiner states, in the section under "Response to Arguments" on page 6 of the present Office Action, that the elements of "industrially prepared triglycerides" in certain ratios are not clearly and explicitly found as examples or embodiments in the specification and that the claims as written are directed to a composition comprising industrially prepared triglycerides which consist essentially of certain fatty acids. In response, Applicants note that the phrase "industrially prepared triglycerides" was previously deleted in the response filed on April 10, 2006. As such, the Examiner's above-mentioned response to arguments does not apply to the claims that were pending when the present Office Action was issued.

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This document is filed timely. No fee is believed to be due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is authorized to deduct said fees from Deposit Account No. 08-3038/13475.0003.PCUS00.

Respectfully submitted,

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Date: August 8, 2006